

strued as an admission that the dietary supplement involved caused or contributed to the adverse event.

**(h) Preemption**

**(1) In general**

No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is different from, in addition to, or otherwise not identical to, this section.

**(2) Effect of section**

**(A) In general**

Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

**(B) Personally-identifiable information**

Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

**(C) Use of safety reports**

Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 379v of this title.

**(i) Authorization of appropriations**

There are authorized to be appropriated to carry out this section such sums as may be necessary.

(June 25, 1938, ch. 675, §761, as added Pub. L. 109–462, §3(a), Dec. 22, 2006, 120 Stat. 3472.)

EFFECTIVE DATE

Section effective 1 year after Dec. 22, 2006, see section 3(d)(1) of Pub. L. 109–462, set out as an Effective Date of 2006 Amendment note under section 343 of this title.

PART I—REAGAN-UDALL FOUNDATION FOR THE  
FOOD AND DRUG ADMINISTRATION

**§ 379dd. Establishment and functions of the  
Foundation**

**(a) In general**

A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this part as the

“Foundation”) shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e).<sup>1</sup> The Foundation shall not be an agency or instrumentality of the United States Government.

**(b) Purpose of Foundation**

The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

**(c) Duties of the Foundation**

The Foundation shall—

(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and predictive tools and devices to measure safety;

(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of title 26 (and exempt from tax under section 501(a) of such title), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

(7) ensure that—

(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

<sup>1</sup> So in original. Probably should be “subsection (g).”

(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

**(d) Board of Directors**

**(1) Establishment**

**(A) In general**

The Foundation shall have a Board of Directors (referred to in this part as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

**(B) Ex officio members**

The ex officio members of the Board shall be the following individuals or their designees:

- (i) The Commissioner.
- (ii) The Director of the National Institutes of Health.
- (iii) The Director of the Centers for Disease Control and Prevention.
- (iv) The Director of the Agency for Healthcare Research and Quality.

**(C) Appointed members**

**(i) In general**

The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 14 individuals, of which 9 shall be from a list of candidates to be provided by the National Academy of Sciences and 5 shall be from lists of candidates provided by patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations. Of such appointed members—

- (I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;
- (II) 3 shall be representatives of academic research organizations;
- (III) 2 shall be representatives of patient or consumer advocacy organizations;
- (IV) 1 shall be a representative of health care providers; and

(V) 4 shall be at-large members with expertise or experience relevant to the purpose of the Foundation.

**(ii) Requirements**

**(I) Expertise**

The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

**(II) Federal employees**

No employee of the Federal Government shall be appointed as a member of the Board under this subparagraph or under paragraph (3)(B).

**(D) Initial meeting**

**(i) In general**

Not later than 30 days after September 27, 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—

- (I) incorporate the Foundation; and
- (II) appoint the members of the Board in accordance with subparagraph (C).

**(ii) Service of ex officio members**

Upon the appointment of the members of the Board under clause (i)(II)—

- (I) the terms of service of the Director of the Centers for Disease Control and Prevention and of the Director of the Agency for Healthcare Research and Quality as ex officio members of the Board shall terminate; and
- (II) the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board, but shall be nonvoting members.

**(iii) Chair**

The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

**(2) Duties of Board**

The Board shall—

(A) establish bylaws for the Foundation that—

- (i) are published in the Federal Register and available for public comment;
- (ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;
- (iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;
- (iv) establish policies that would subject all employees, fellows, and trainees of the

Foundation to the conflict of interest standards under section 208 of title 18;

(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;

(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

(x) specify a process for annual Board review of the operations of the Foundation; and

(xi) establish specific duties of the Executive Director;

(B) prioritize and provide overall direction to the activities of the Foundation;

(C) evaluate the performance of the Executive Director; and

(D) carry out any other necessary activities regarding the functioning of the Foundation.

### **(3) Terms and vacancies**

#### **(A) Term**

The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

#### **(B) Vacancy**

Any vacancy in the membership of the Board—

(i) shall not affect the power of the remaining members to execute the duties of the Board; and

(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

### **(C) Partial term**

If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

### **(D) Serving past term**

A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

### **(4) Compensation**

Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

### **(e) Incorporation**

The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

### **(f) Nonprofit status**

In carrying out subsection (b), the Board shall establish such policies and bylaws under subsection (d), and the Executive Director shall carry out such activities under subsection (g), as may be necessary to ensure that the Foundation maintains status as an organization that—

(1) is described in subsection (c)(3) of section 501 of title 26; and

(2) is, under subsection (a) of such section, exempt from taxation.

### **(g) Executive Director**

#### **(1) In general**

The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

#### **(2) Compensation**

The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

### **(h) Administrative powers**

In carrying out this part, the Board, acting through the Executive Director, may—

(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

(3) prescribe the manner in which—

(A) real or personal property of the Foundation is acquired, held, and transferred;

(B) general operations of the Foundation are to be conducted; and

(C) the privileges granted to the Board by law are exercised and enjoyed;

(4) with the consent of the applicable executive department or independent agency, use

the information, services, and facilities of such department or agencies in carrying out this section;

(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;

(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

**(i) Acceptance of funds from other sources**

The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

**(j) Service of Federal employees**

Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

**(k) Detail of Government employees; fellowships**

**(1) Detail from Federal agencies**

Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

**(2) Voluntary service; acceptance of Federal employees**

**(A) Foundation**

The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

**(B) Food and Drug Administration**

The Commissioner may accept the uncompensated services of Foundation fellows or

trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 379 of this title.

**(l) Annual reports**

**(1) Reports to Foundation**

Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

**(2) Report to Congress and the FDA**

Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

**(m) Separation of funds**

The Executive Director shall ensure that the funds received from the Treasury are held in separate accounts from funds received from entities under subsection (i).

**(n) Funding**

From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than \$500,000 and not more than \$1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).

(June 25, 1938, ch. 675, § 770, as added Pub. L. 110-85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890.)

**§ 379dd-1. Location of Foundation**

The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

(June 25, 1938, ch. 675, § 771, as added Pub. L. 110-85, title VI, § 601(b), Sept. 27, 2007, 121 Stat. 897.)

**§ 379dd-2. Activities of the Food and Drug Administration**

**(a) In general**

The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 379dd(l)(2) of this title.

**(b) Report to Congress**

Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report